

AMENDMENTS TO THE CLAIMS

1-9 (Canceled)

10. (Currently Amended) A process for preparing crystallised agglomerates comprising an alkali metal clavulanate salt, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded, which comprises stirring a solvent and antisolvent mixture of an alkali metal clavulanate salt [[a clavulanate in a liquid phase]].

11. (Canceled)

12. (Currently Amended) A process according to claim [[11]] 10, wherein the ratio of the weight of the solvent containing [[β -lactam]] the clavulanate salt to the anti-solvent is about 0.05 to 10 wt.%.

13. (Currently Amended) A process according to claim [[11]] 10, wherein the solvent is selected from the group consisting of water, alcohol, ketone and ester or a mixture thereof, wherein water is present in said mixture.

14. (Previously Presented) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture of these anti-solvents, optionally containing water.

16. (Previously Presented) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Previously Presented) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (Previously Presented) A process according to claim 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Previously Presented) A process according to claim 18, wherein the agglomerates have an average particle size between about 1 μm and 1500 μm .

20. (Currently Amended) A process according to claim [[11]] 10, wherein the process comprises dissolving [[one or more β -lactams]] the alkali metal clavulanate salt in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

25. (canceled)

27. (Previously Presented) A process according to claim 19, wherein the agglomerates have an average particle size about 100 μm .

28. (Previously Presented) A process according to claim 19, wherein the agglomerates have an average particle size about 1000 μm .

29. (Previously Presented) A process according to claim 10, wherein the agglomerates have a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (Currently Amended) A process according to claim 10, wherein the agglomerates have improved flowability relative to clavulanate needles obtained without stirring the alkali metal clavulanate salt in a solvent and antisolvent mixture, as measured using identical procedures.

31. (Currently Amended) A process according to claim 10, wherein the agglomerates have reduced compressibility [[between 10 % and 40 %]] relative to clavulanate needles obtained without stirring the alkali metal clavulanate salt in a solvent and antisolvent mixture, as measured using identical procedures.

32. (Currently amended) A process according to claim 10, wherein said alkali metal clavulanate [[comprises a clavulanate]] salt is potassium clavulanate [[salt]].

33. (canceled)

34. (Currently Amended) A process according to claim [[33]] 10, wherein the agglomerates further comprise amoxicillin.

35. (Currently Amended) A process according to claim 10, wherein the agglomerates [[optionally]] further contain one or more excipients.

36. (Previously Presented) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

37. (Currently Amended) An agglomerate of clavulanates obtained from the process of claim 10[[, wherein said agglomerate has a bulk density of between about 0.2 g/mL and 0.6 g/mL, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded]]].

38. (Currently Amended) The agglomerate of claim 37, wherein said agglomerate has [[a]] reduced compressibility [[of between about 10 and 40 %]] relative to clavulanate needles obtained without stirring the alkali metal clavulanate salt in a solvent and antisolvent mixture, as measured using identical procedures.

39. (Previously Presented) The agglomerate of claim 37, further comprising amoxillin.

40. (Previously Presented) The agglomerate of claim 37, further comprising one or more excipients.

41. (Previously Presented) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (Previously Presented) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (Previously Presented) The agglomerate of claim 42, wherein said agglomerates has an average particle size of about 100 μm .

44. (Previously Presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μ m.

45. (Currently Amended) The agglomerate of claim 37, wherein said agglomerate has improved flowability relative to clavulanate needles obtained without stirring the alkali metal clavulanate salt in a solvent and antisolvent mixture, as measured using identical procedures.

46. (Currently Amended) The agglomerate of claim 37, wherein said [[clavulanates comprise]] alkali metal clavulanate salt is potassium clavulanate.

47. (Previously Presented) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (Previously Presented) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (Previously Presented) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (Previously Presented) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.

Please add the following new claim:

51. (New) The agglomerate of claim 37, wherein the agglomerate has a bulk density of between about 0.2 g/mL and 0.6 g/mL.